REMARKS

Applicant's representative appreciates the Examiner extending the courtesy of a personal interview on May 11, 2006. Applicant's representative agrees with the Examiner's Interview Summary mailed May 19, 2006.

Claims 1 and 22 are amended. Claims 20, 21, 24 and 30 are cancelled. Claims 1, 4, 7-11, 13 and 20-29 stand rejected. By this amendment, Claims 1, 4, 7-11, 13, 22, 23, and 25-29 are pending.

Claim Rejections under 35 U.S.C. § 102(a)

Claims 1, 4, 7, 13, 20-22, 28-30 are rejected under 35 U.S.C. §102(a) as being anticipated by Bisson (FR 2785811, published May 19, 2000, hereinafter *Bisson*). Claims 8-11 and 23-27 are not rejected.

Claim 1 has been amended to recite biocompatible micronized high density polyethylene particles having a size greater than one-hundred microns. Support for this amendment is found in the specification on page 4, paragraph 49. *Bisson's* particles are less than one-hundred microns. On page 2, next to the last paragraph, *Bisson* discloses particle diameters of more than approximately 10 microns, in particular 30-100 microns, preferably 30-60 microns. *Bisson* teaches away from using particles with diameters greater than 100 microns (see the French version of *Bisson* page 2, line 19, and the English version of *Bisson* page 3 second paragraph) which recites the disadvantages of using particles with diameters more than 100 microns as they risk giving the tissue a "visually perceivable roughness"). {Applicant submits both the French and English versions of *Bisson* as Exhibit A for the Examiner's convenience{ Applicant wishes to point out that this 100 microns (see the French version of *Bisson* page 2, line 19) was incorrectly translated in the English version as 1000 microns (page 3, second paragraph). *Bisson* further teaches away from using particles with diameters more than 100 microns in this paragraph by stating that it would be more difficult to inject the product through a

needle. Applicant respectfully asserts that amended Claim 1 is novel over *Bisson* and requests withdrawal of the rejection of Claim 1 and its dependent claims.

Claim 22 has been amended to include limitations found in Claim 24, namely the K values of polyvinylpyrrolidone. Claim 24 was not rejected in view of *Bisson*. Accordingly, amended Claim 22 is novel over *Bisson* and Applicant requests withdrawal of the rejection of Claim 22 and its dependent claims.

Claim rejections under 35 U.S.C. §112, first paragraph

In the Office Action Claims 1, 4, 7-11, 13 and 20-30 were rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor had possession of the claimed invention at the time the application was filed. This is a new matter rejection. Applicant traverses and asserts that he was in possession of the claimed invention at the time the application was filed for at least the following reasons.

The specification discloses solid polymer particles as biocompatible (micronized) polyethylene particles made from MEDPOR in paragraphs 0030, 0043 and 0058 and in the Abstract. The polyethylene in MEDPOR is high density polyethylene (HDPE), as declared by the Applicant previously (January, 2006) and as known to one of ordinary skill in the art. The Declarations of Applicant and Dr. Perkins filed in January, 2006, both describe Applicant's disclosure of his claimed invention in December of 1999, comprising high density polyethylene particles in a carrier for use in soft tissue augmentation.

One of ordinary skill in the art referred to MEDPOR as high density polyethylene before and after the filing of this patent application. Applicant submits three articles attached as Exhibits A, B, and C which demonstrate this fact. In Exhibit B (Lacey et al., The Journal of Craniofacial Surgery, vol. 4, pp 74-78, 1993), Lacey mentions on page 74, second column, third paragraph, that porous high density polyethylene (MEDPOR) provides the standard of biocompatibility. In Exhibit C (Williams et al., Arch. Otolaryngol. Head & Neck Surgery, vol. 123, pp. 578-583, 1997) Williams discloses

porous high density polyethylene (MEDPOR) implants (see Objective, pp 578). In Exhibit D (Lee et al., Arch Otolaryngol. Head & Neck Surgery, vol. 131, pp. 578-583, 2005), Lee describes use of porous high density polyethylene (MEDPOR) on page 446, column 2, and in the figure legends. Accordingly, one of skill in the art knows and knew before the application was filed that MEDPOR is high density polyethylene. Please see the concurrently filed Declaration of Dr. Robert D. Wallace attesting to this statement.

Therefore, by reciting "MEDPOR (biocompatible (micronized) polyethylene)", Applicant was de facto referring to HDPE. Applicant was in possession of his claimed invention comprising biocompatible micronized high density polyethylene particles when he referred to MEDPOR (biocompatible (micronized) polyethylene) in the patent application. Further, Applicant was in possession of his claimed invention comprising biocompatible micronized high density polyethylene particles when he disclosed this invention to Dr. Perkins in December of 1999.

The Examiner implies that HDPE is a chemical genus composed of various species and seems to assert that Applicant is trying to claim a genus. The Examiner notes that HDPE is produced in many forms, most of which are not suitable for surgery, and mentions various forms that are used in Tupperware, milk cartons, plastic bags, etc. Applicant responds that MEDPOR Biomaterial (whether in the porous or non-porous form), Tupperware, milk cartons or any other forms of HDPE products are not different species of the genus "high-density" polyethylene. These items are all made of the same material, HDPE, but they are processed differently. Therefore, Tupperware, milk cartons, MEDPOR, etc. are not different forms of HDPE. Instead, HDPE is processed differently to create different products. The grade of HDPE, which is used to make implantable MEDPOR implants, is currently used across the plastics industry to make a wide range of products outside the medical field. High-density polyethylene is synthesized as flakes or powder. This powder is then processed to various extents based on the final application (e.g., containers or MEDPOR implants). Based on the final application, HDPE will be subjected to various manufacturing processes such as injection molding, blow molding, compression molding, sintering, etc. If the HDPE-containing article is intended to be implanted, it will be made in an anatomical shape and sterilized.

If the HDPE-containing article is intended to be used as a container, it will be made in a suitable shape and will not be sterilized.

The Examiner asserted that "...high density polyethylene is produced in many forms, most of which are not suitable for surgery...". Applicant responds that the HDPE used to make consumer products can and is indeed used to make implants suitable for surgery. It is the chemical structure, not the process, which renders HDPE biocompatible.

The Ho, T. "Biopolymers in Otolaryngology" Baylor College of Medicine reference used by the examiner that states "...only "porous" high-density polyethylene is used in surgery because it allows "soft tissue ingrowth"..." is not accurate as non-porous forms of HDPE are used in surgery (see MEDPOR BARRIER implants from Porex Surgical Group). This further proves that the chemical structure of implants, not their process of manufacture, confers biocompatibility.

The Examiner implies that HDPE is a chemical genus composed of various species and seems to assert that Applicant is trying to claim a genus. The analogy used is halogens (the genus) being composed of species (F, Cl, Br, etc.). According to the examiner, MEDPOR, Tupperware, milk cartons, etc., are species of the genus HDPE. Applicant respectfully traverses for the following reasons. F, Cl, Br, all have different chemical structures and are different species that belong to a chemical group (or genus) called halogens. Applicant asserts that HDPE is a species within the genus of polyethylene. Other species within the genus of polyethylene include low density polyethylene, linear low density polyethylene and ultra high molecular weight polyethylene . MEDPOR, Tupperware, and milk cartons made of HDPE all have the same chemical structure. What differentiates these products is the way they are processed, not their chemical structures. Therefore, these products are not different species within a chemical genus. The same grade of HDPE can be (and is) used to make consumer products as well as implants. HDPE is the starting material to make these different objects, these objects are not different types of HDPE.

Accordingly, Applicant's invention, as claimed, was in Applicant's possession at the time of filing the application and the claims do not recite a genus. Accordingly, in view of these remarks and identified support in the specification, Applicant respectfully

asserts that the rejection of Claims 1, 4, 7-11, 13 and 20-30 under 35 U.S.C. §112, first paragraph, has been overcome and requests its withdrawal.

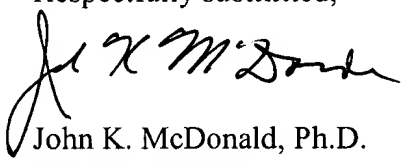
CONCLUSION

Based upon the amendments and remarks provided above, Applicant believes the pending Claims are in condition for allowance. A Notice of Allowance is therefore respectfully solicited.

This response is considered timely filed and fully responsive to the Office Action of April 27, 2006. No additional fees are believed due; however, the Commissioner is hereby authorized to charge any additional fees that may be required, or credit any overpayment, to Deposit Account No. 11-0855.

If the Examiner believes any informalities remain in the application that may be corrected by Examiner's Amendment, or there are any other issues that can be resolved by telephone interview, a telephone call to the undersigned attorney at (404) 745-2470 is respectfully solicited.

Respectfully submitted,



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